IV. 510(k) Summary

JUL 2 5 2002

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

A. Date Prepared

June 28, 2002

B. General Information

Manufacturer: Parallax Medical, Inc.
940 Disc Drive
Scotts Valley, CA 95066-4544

Contact: Richard M. Ruedy
Director, Regulatory and Clinical Affairs
(831) 439-0130 phone
(831) 439-1725 fax

C. Device Information

Trade Name:	Clearview Plus Bone and Vertebral Body Biopsy Needles
Common Name:	Bone Biopsy Needle
Device Classification:	II
Classification Name:	Gastroenterology-Urology Biopsy Instrument
Product Code(s):	78 KNW
Classification Regulation:	
	21 CFR §876.1075 – Gastroenterology-urology biopsy instrument

D. Predicate Device Identification

The subject device is substantially equivalent to Clearview Bone and Vertebral Body Biopsy Needles (K011206, July 18, 2001).

E. Intended Use

Clearview Plus Bone and Vertebral Body Biopsy Needles are intended for use by a physician performing bone or vertebral body biopsy using a coring (cutting) or aspiration technique.

F. Product Description

The Clearview Bone and Vertebral Body Biopsy Needles consist of a cannula/stylet assembly in 11 and 13 gauge configurations. The needles have a useable length of 4.565 in (11.6 cm).

The modified Clearview Plus Bone and Vertebral Body Biopsy Needles consist of a cannula/stylet assembly and are available in an 11 gauge configuration. The additional components include:

- 10cc VacLok syringe
- Luer cap
- 13.5 gauge inner cannula (useable length 5.355 in, 13.6 cm)

The needles useable length of 4.565 in (11.6 cm) is the same for the original design and for the modified design. The modified product and the original product are both provided sterile and for single use only.

G. Substantial Equivalence

The subject device is equivalent in intended use, design, and technological characteristics to the Clearview Bone and Vertebral Body Biopsy Needles, K011206.

H. Summary

Based on the information provided in this notification, the subject device is substantially equivalent to the predicate devices in intended use, technological characteristics, and design.

I. Signature of Preparer

The 510(k) summary was prepared and submitted by the following Parallax Medical employee.

Richard M. Ruedy
Director, Regulatory and Clinical Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 5 2002

Parallax Medical, Inc.
Richard M. Ruedy
Director, Regulatory and Clinical Affairs
940 Disc Drive
Scotts Valley, California 95066-4544

Re: K022169
Trade Name: Clearview Plus Bone and Vertebral Body Biopsy Needles
Regulation Number: 876.1075
Regulation Name: Gastroenterology/Urology Biopsy Instrument
Regulatory Class: II
Product Code: KNW
Dated: July 2, 2002
Received: July 3, 2002

Dear Mr. Ruedy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Statement of Indications for Use

Indications for Use

510(k) Number (if known): K022169

Device Name: Clearview Plus Bone and Vertebral Body Biopsy Needles

Indications for Use:

Clearview Plus Bone and Vertebral Body Biopsy Needles are intended for use by a physician performing bone or vertebral body biopsy using a coring (cutting) or aspiration technique.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022169

Prescription Use ✓ OR Over-The Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)